



Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

[60Day-13-13XA]

Proposed Data Collections Submitted for
Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Ron Otten, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Improving HIV Prevention and Treatment Outcomes Among HIV-Infected Persons by Integrating Community Pharmacists and Clinical Sites into a Model of Patient-Centered HIV Care - New - National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Medication Therapy Management (MTM) is a group of pharmacist provided services that is independent of, but can occur in conjunction with, provision of medication. Medication Therapy Management encompasses a broad range of professional activities and cognitive services within the licensed pharmacists' scope of practice and can include monitoring prescription filling patterns and timing of refills, checking for medication interactions, patient education, and monitoring of patient response to drug therapy.

HIV specific MTM programs have demonstrated success in improving HIV medication therapy adherence and persistence.

While MTM programs have been shown to be effective in increasing medication adherence for HIV-infected persons, no MTM programs have been expanded to incorporate primary medical providers in an effort to establish patient-centered HIV care. To address this problem CDC has entered into a public-private partnership with Walgreen Company (a.k.a Walgreens pharmacies, a national retail pharmacy chain) to develop and implement a model of HIV care that integrates community pharmacists with primary medical providers for patient-centered HIV care. The model program will be implemented in ten sites and will provide patient-centered HIV care for approximately 1,000 persons.

The patient-centered HIV care model will include the core elements of MTM as well as additional services such as individualized medication adherence counseling, active monitoring of prescription refills and active collaboration between pharmacists and medical clinic providers to identify and resolve medication related treatment problems such as treatment effectiveness, adverse events and poor adherence. The expected outcomes of the model program are increased retention in HIV care, adherence to HIV medication therapy and viral load suppression.

CDC requests OMB approval to collect standardized information, from ten project sites over the three year project period. CDC also requests approval to conduct one cycle of

retrospective data collection during the first year of the three year project period. The retrospective data collection will provide information about clients' baseline characteristics prior to participation in the model program which is needed to compare outcomes before and after program implementation.

Pharmacy, laboratory and medical data will be collected through abstraction of all participant clients' pharmacy and medical records. Pharmacy, laboratory and medical data are needed to monitor retention in care, adherence to therapy, viral load suppression and other health outcomes. Program specific data, such as the number of MTM elements completed per project site will be collected by program. Qualitative data will be gathered from program staff through in-person or telephone interviews.

The data collection will allow CDC to conduct continuous program performance monitoring which includes identification of barriers to program implementation, solutions to those barriers, and documentation of client health outcomes. Performance monitoring will allow the model program to be adjusted, as needed, in order to develop a final implementation model that is self-sustaining and which can be used to establish similar collaborations in a variety of clinical settings. There is no cost to participants other than their time.

Estimated Annualized Burden Hours

Type of respondent	Form Name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Clinic Data Manager	Project clinic characteristics form	10	1	30/60	5
Pharmacist	Project pharmacy characteristics form	10	1	30/60	5
Clinic Data Manager	Initial medical abstraction form	10	1	50	500
Clinic Data Manager	Follow-up medical abstraction form	10	4	25	1,000
Pharmacist	Pharmacy abstraction form	10	4	25	1,000
Clinic and pharmacy staff	Interview form	60	4	45/60	180
Total					2,690

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Centers for Disease Control and Prevention

[FR Doc. 2013-14435 Filed 06/17/2013 at 8:45 am; Publication Date: 06/18/2013]